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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,284	11/27/2001	Alexander M. Rubenchik	P1-33	2363

7590 08/26/2004

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EXAMINER	
CHATTOPADHYAY, URMI	
ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 08/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/995,284	RUBENCHIK ET AL.	
	Examiner	Art Unit	
	Urmi Chattopadhyay	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,10-22,25-32,42 and 44-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10-22,25-32,42 and 44-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed 5/5/04 has been entered. The changes to the abstract and specification have been approved by the examiner. Claims 8, 9, 23, 24, 33-41 and 43 have been canceled, and new claim 46 has been added. All pending claims are being considered for further examination on the merits, which are claims 1-7, 10-22, 25-32, 42 and 44-46.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 46 recites the limitation "said apparatus" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-3, 10-14, 42 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weissman et al. (USPN 6,308,715 B1) in view of Buscemi et al. (USPN 6,387,124 B1).

Weissman et al. disclose an apparatus and method of preparing a patient for detection of in-stent restenosis with all the elements of claims 1 and 42, but are silent to a means for enhancing microwave radiation that is scattered from the stent, wherein the means produces a larger scattered microwave radiation field over that which would occur from the stent absent the means. See column 7, lines 8-11 and Figure 1 for an implanted cardiovascular stent (claim 14) being made of a conductive metal, which is a microwave scattering material, according to page 6, line 2 of applicant's specification. See column 7, lines 14 and 61-63 for the stent having a resonant frequency. See columns 7-8, lines 59-57 for a diagnostic that is operationally responsive to the resonant frequency. Buscemi et al. disclose a stent comprising a cylindrical symmetry variation (claim 2), specifically a gap along the cylindrical axis of the stent (claim 3) in order to permit compression or reduction of the effective diameter of the stent. See column 5, lines 50 and 57-58 and Figure 1 for slot (26). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Buscemi et al. to modify the metal stent of Weissman et al. by including a gap along the cylindrical axis of the stent in order to permit compression or reduction of the effective diameter of the stent, which would aid in stent delivery (claim 13). The presence of this gap would by nature enhance the microwave radiation that is scattered from the stent and would produce a larger scattered microwave radiation field over that which would occur from the stent absent the gap. Also, the gap in the stent meets the limitations of the means comprising a dimension (gap) that is tuned to maximize

the detection of in-stent restenosis (claim 10), tuned for at least on microwave frequency (claim 11), and tuned for at least one desired frequency (claim 12).

Claim 46, see column 7, lines 14-28 for the resonant frequency shifting as the stent collects plaque and column 8, lines 29-43 for means for calculating the shift.

6. Claims 4-7, 15-17, 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weissman et al. and Buscemi et al. as applied to claim 1 above, and further in view of Haddad et al. (USPN 6,233,479 B1).

Weissman et al., as modified by Buscemi et al., disclose an apparatus with all the elements of claim 1, but are silent to the transmitter and receiver transmitting and receiving, respectively, microwave radiation, as required by claims 4 and 5. See column 4, lines 32-44 and column 5, lines 16-20 and 21-34 for a transmitter (38) transmitting acoustic energy to the stent so that the stent produces scattered or reflected acoustic energy, and a receiver (38) receiving data comprising the scattered or reflected acoustic energy. See column 10, lines 60-65 for the transmitter and receiver being polarization sensitive (claim 45). Haddad et al. teach a detector which uses a microwave radiation transmitter and scattered/reflected microwave radiation receiver, which operate at a frequency of ~3.5 GHz (claim 44), in order to detect hematomas or plaque (occlusion) in the carotid artery. See column 5, lines 3-6, column 4, line 20 and column 2, lines 44-45. Both Weissman et al., as modified by Buscemi et al., and Haddad et al. use transmitters and receivers to perform the same function of detecting occlusions in a vessel by measuring the change in energy or radiation received by the receiver. Because applicant has not disclosed that microwave radiation for restenosis detection provides an advantage, is used for a

particular purpose, or solves a stated problem over the acoustic energy used for restenosis detection of the prior art, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the polar sensitive transmitter and receiver of Weissman et al. and Buscemi et al. transmit and receive microwave radiation to detect restenosis.

Weissman et al., as modified by Buscemi et al., disclose computer hardware with software comprising an algorithm to analyzing the data to determine whether in-stent restenosis has occurred and to quantify the amount of in-stent restenosis, as required by claims 6 and 7. See column 2, lines 40-56. Weissman et al. and Buscemi et al. are silent to the apparatus further comprising an alarm triggered by the algorithm if in-stent restenosis is present or exceeds a preset level, as required by claims 15-17. Haddad et al. teach an alarm triggered by an algorithm to indicate the presence of a hematoma, thereby exceeding the preset level of the baseline. See column 4, lines 7-16. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Haddad et al. to include an alarm to the apparatus of Weissman et al. and Buscemi et al. in order to indicate to the operator the presence of restenosis.

7. Claims 18, 19 and 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weissman et al. in view of Haddad et al.

Weissman et al. disclose an apparatus with all the elements of claim 18, but are silent to the transmitter and receiver transmitting and receiving, respectively, microwave radiation. See column 2, lines 2-3 for a stent, and column 4, lines 32-44, column 5, lines 16-20 and 21-34 for a transmitter (38) operatively connected to the stent and configured to transmit acoustic energy to

the stent so that the stent produces scattered or reflected acoustic energy, and a receiver (38) operatively connected to the stent and configured to receive data comprising acoustic energy scattered from the stent. See column 7, lines 14 and 61-63 for the stent having a resonant frequency. See columns 7-8, lines 59-57 for a diagnostic that is operationally responsive to the resonant frequency. Haddad et al. teach a detector which uses a microwave radiation transmitter and scattered/reflected microwave radiation receiver in order to detect hematomas or plaque (occlusion) in the carotid artery. See column 5, lines 3-6, column 4, line 20 and column 2, lines 44-45. Both Weissman et al. and Haddad et al. use transmitters and receivers to perform the same function of detecting occlusions in a vessel by measuring the change in energy or radiation received by the receiver. Because applicant has not disclosed that microwave radiation for restenosis detection provides an advantage, is used for a particular purpose, or solves a stated problem over the acoustic energy used for restenosis detection of the prior art, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the transmitter and receiver of Weissman et al. transmit and receive microwave radiation to detect restenosis.

Weissman et al. disclose computer hardware with software comprising an algorithm to analyzing the data to determine whether in-stent restenosis has occurred, as required by claim 19. See column 2, lines 40-56. Weissman et al. are silent to the apparatus further comprising an alarm triggered by the algorithm if in-stent restenosis is present or exceeds a preset level, as required by claims 30-32. Haddad et al. teach an alarm triggered by an algorithm to indicate the presence of a hematoma, thereby exceeding the preset level of the baseline. See column 4, lines 7-16. It would have been obvious to one of ordinary skill in the art at the time of applicant's

invention to look to the teachings of Haddad et al. to include an alarm to the apparatus of Weissman et al. in order to indicate to the operator the presence of restenosis.

Claim 28, see column 7, lines 8-13 for stent being a convention stent. The examiner contends that it is old and well known in the art for stents to have a compact state with a first cross-sectional area for stent delivery and an expanded state with a second, larger cross-sectional area for vessel support. Therefore, the conventional stent of Weissman et al. meets these limitations of claim 28.

Claim 29, see Figure 1 for stent being a cardiovascular stent.

8. Claims 20-22 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weissman et al. and Haddad et al., as applied to claim 18 above, and further in view of Buscemi et al.

Weissman et al., as modified by Haddad et al., disclose an apparatus with all the elements of claim 18, but are silent to a means for enhancing microwave radiation that is scattered from the stent, wherein the means produces a larger scattered microwave radiation field over that which would occur from the stent absent the means, as required by claim 20. See column 7, lines 8-11 for a stent being made of a conductive metal, which is a microwave scattering material, according to page 6, line 2 of applicant's specification. Buscemi et al. disclose a stent comprising a cylindrical symmetry variation (claim 21), specifically a gap along the cylindrical axis of the stent (claim 22) in order to permit compression or reduction of the effective diameter of the stent. See column 5, lines 50 and 57-58 and Figure 1 for slot (26). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the

teachings of Buscemi et al. to modify the metal stent of Weissman et al. and Haddad et al. by including a gap along the cylindrical axis of the stent in order to permit compression or reduction of the effective diameter of the stent, which would aid in stent delivery. The presence of this gap would by nature enhance the microwave radiation that is scattered from the stent and would produce a larger scattered microwave radiation field over that which would occur from the stent absent the gap. Also, the gap in the stent meets the limitations of the means comprising a dimension (gap) that is tuned to maximize the detection of in-stent restenosis (claim 25), tuned for at least on microwave frequency (claim 26), and tuned for at least one desired frequency (claim 27).

Response to Arguments

9. Applicant's arguments with respect to claims 1, 18 and 42 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.

Urmi Chattopadhyay

Art Unit 3738

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